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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,257	04/23/2001	Robert A. Scott	6512-11EJF	7160

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EXAMINER	
HON, SOW FUN	

ART UNIT	PAPER NUMBER
1772	12

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,257	SCOTT ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/02 has been entered.

Withdrawn Rejections

2. The 35 U.S.C. rejections of claims 1-56 have been withdrawn due to cancellation of said claims.

New Rejections

Claim Objections

3. Claim 69 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 69 depends on claim 68 and recites xanthan which is present in both claims, but also recites polysaccharides which are not present in claim 68. The relationship between the two Markush groups is not defined in order to distinguish which group is the subset for the dependency of claim 69 on claim 68 to be proper.

4. Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 70 depends on claim 69, and recites gellan which is present in claim 69. Claim 70, however, also recites kappa-carrageenan and locus bean gum which are only present in claim 68, and konjac mannan which is not recited in claim 69.

5. Claim 76 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 76 depends on claim 75 and recites colors which are combinations of different dyes, oxides and hydroxides present in claim 75. However, the relationship between the two Markush groups is not defined in order to distinguish which group is the subset for the dependency of claim 76 on claim 75 to be proper.

6. Claim 77 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 77 depends on claim 76, and recites titanium dioxide which is already present in claim 75. In addition, since claim 76 is dependent on claim 75, and claim 76 recites other coloring agents, it is unclear which Markush group is the subset. Perhaps claim 77 should depend on claim 74?

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 57, 60-63, 67-69, 72-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Jordan.

Jordan teaches a moisture barrier film coating which uses a liquid coating solution which comprises polyvinyl alcohol (PVA), soya lecithin (plasticizer and sequestering agent), coloring agent (colorant) of iron oxide, titanium dioxide or natural colors and exocellular polysaccharides which are a subset of hydrolloids, such as alginates and natural gums (plasticizer) (column 2, lines 15-65). The amount of PVA is 30 to 99 %, coloring agent 0 to 60 %, plasticizer 0.2 to 10 %, 0 to 2 % of alginates (hydrocolloid suspending agent) (column 3, lines 1-10). Tartrazine aluminum contains aluminum cations which would comprise less than 5% (less than a third of the 14 weight % of the salt component (column 5, lines 50-60). Xanthan (gum) (exocellular polysaccharide) is present in one of the examples (column 3, lines 30).

Jordan teaches that the liquid solution is sprayed onto the pharmaceutical tablets, effectively encapsulating and thus containing each tablet (column 3, lines 50-60), thereby effectively forming an encapulator container. Although the capsule was not formed via the process of dipmolding to form two halves, and then sealing two halves together by a liquid fusion process, even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985)*. The final product is still a whole capsule.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 58-59, 63-70, 72-74, 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deters et al. (US 4,627,850) in view of Yamamoto.

Deters et al. teaches embodiments of a hard capsule and a soft capsule. The hard capsules are made by dipmolding (column 3, lines 55-65). In the instant case, sealing two halves together by a liquid fusion process produces a final product which is indistinguishable from a whole capsule.

Deters et al. teaches a capsule with a first lamina 33 formed of polyvinyl alcohol (column 9, lines 10-30) (a hydrophillic polymeric composition (column 5, lines 10-40) and coated with hydroxypropyl methylcellulose phthalate (column 8, lines 20, 40-60) (lamina 34 comprising a semipermeable polymeric composition) (column 8, lines 10-25). A plasticizer such as glycerol (glycerine), triethyl citrate (respective salt of citric acid) is optionally added to the polyvinyl alcohol in the amount of 0.05 to 30 % by weight of the capsule (composition) (column 9, lines 60-68 and column 10,lines 1-5).

Deters et al., however, fails to teach the setting system for the polyvinyl alcohol lamina.

Yamamoto et al. teaches a capsule for pharmaceutical use (title). The capsule comprises a film-forming polymer (water-soluble cellulose derivative) and a setting (gelatinizing) agent

(abstract). The setting agents disclosed are polysaccharide hydrocolloids such as kappa-carrageenan and the cations listed (column 3, 1-20). Other hydrocolloids taught are polysaccharides of tamarind seed (tamarind gum) and curdlan (column 3, lines 1-4). Yamamoto et al. teaches that the amount of film forming polymer is 92 to 94 %, the amount of hydrocolloid (setting (gelatinizing) agent) is 0.1 to 0.5 % by weight, the amount of cation (auxilliary) is 0.01 to 0.5 % by weight and the amount of water is 4 to 6 % by weight of the capsule film (column 4, lines 25-40) in order to obtain a good hard capsule film via dip molding (conventional immersion molding method) (column 3, lines 40-68).

Yamamoto et al. discloses prior art which teaches polyvinyl alcohol as a film forming polymer. Yamamoto et al. teaches that the capsule molding steps of the prior art (column 1, lines 50-68) failed due to the inability of the composition to set (gelate) at room temperature (column 2, lines 40-55). It can then be inferred that the amounts of the setting (gelatinizing) agent, cations and water would form a superior capsule when added to the polyvinyl alcohol in the prior art.

Because Yamamoto et al. teaches that the concerted amounts of the film forming polymer, setting agent, the cations and water are needed in order to obtain a good hard capsule film via dip molding, and discloses prior art which has polyvinyl alcohol as a film forming polymer, it would have been obvious to one of ordinary skill in the art to have added the amounts taught by Yamamoto et al. for the setting agent, cations and water to the polyvinyl alcohol lamina in the capsule of Deters et al. in order to obtain a good capsule via dip molding.

11. Claims 63-70, 72-78, 80-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan in view of Yamamoto et al.

Jordan teaches a moisture barrier film coating which uses a liquid coating solution which comprises polyvinyl alcohol, soya lecithin (plasticizer and sequestering agent), coloring agent (colorant) of iron oxide, titanium oxide or natural colors and exocellular polysaccharides which are a subset of hydrolloids, such as alginates and natural gums (plasticizer) (column 2, lines 15-65). The amount of polyvinyl alcohol is 30 to 99 %, coloring agent 0 to 60 %, plasticizer 0.2 to 10 %, 0 to 2 % of alginates (hydrocolloid suspending agent) (column 3, lines 1-10). Tartrazine aluminum contains aluminum cations which would comprise less than 5% (less than a third of the 14 weight % of the salt component (column 5, lines 50-60). Xanthan (gum) (exocellular polysaccharide) is present in one of the examples (column 3, lines 30).

Jordan teaches that the liquid solution is sprayed onto the pharmaceutical tablets, effectively encapsulating and thus containing each tablet (column 3, lines 50-60), thereby forming a capsule. Although Jordan fails to teach dipmolding as a means of forming the capsule, it would have been an obvious variation in the art to form the capsule by dipmolding the composition onto the tablets instead of spraying.

Jordan, however, fails to teach kappa-carrageenan as one of the polysaccharide hydrocolloids, and an amount of water in the capsule composition.

Yamamoto et al. teaches a capsule for pharmaceutical use (title). The capsule comprises a film forming polymer (water-soluble cellulose derivative) and a setting (gelatinizing) agent (abstract). The setting agents disclosed are polysaccharide hydrocolloids such as the preferred kappa-carrageenan and the cations listed (column 3, 1-20). Other hydrocolloids taught are polysaccharides of tamarind seed (tamarind gum) and curdlan (column 3, lines 1-4). Yamamoto et al. teaches that the amount of film forming polymer is 92 to 94 %, the amount of setting

(gelatinizing) agent is 0.1 to 0.5 % by weight, the amount of cation (auxilliary) is 0.01 to 0.5 % by weight and the amount of water is 4 to 6 % by weight of the capsule film (column 4, lines 25-40) in order to obtain a good hard capsule film via dip molding (conventional immersion molding method) (column 3, lines 40-68).

Yamamoto et al. discloses prior art which teaches polyvinyl alcohol as a film forming polymer. Yamamoto et al. teaches that the capsule molding steps of the prior art (column 1, lines 50-68) failed due to the inability of the composition to set (gelate) at room temperature (column 2, lines 40-55). It can then be inferred that the amounts of setting (gelatinizing) agent, cations and water would form a superior capsule when added to the polyvinyl alcohol in the prior art.

Because Yamamoto et al. teaches that kappa carrageenan is a preferred hydrocolloid setting agent, that the concerted amounts of the film forming polymer, the setting agent, the cations and water are needed in order to obtain a good hard capsule film via dip molding, and discloses prior art which teaches polyvinyl alcohol as a film forming polymer, it would have been obvious to one of ordinary skill in the art to have used the preferred kappa carrageenan hydrocolloid setting agent and water, and the concerted amounts of the film forming polymer, the setting agent, the cations and water taught by Yamamoto et al. in the capsule of Jordan in order to obtain a good capsule via dip molding.

12. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jordan in view of Frensch et al.

Jordan has been discussed above, and teaches the polyvinyl alcohol film capsule. Jordan fails to teach the addition of an antifoaming agent.

Frensch et al. teaches microcapsules having a container (shell) consisting of water-soluble polyvinyl alcohol (PVA) encapsulating pharmaceuticals (column 2, lines 25-60). A suitable antifoaming agent is added during mixing of the components of the encapsulating dispersion to suppress disturbing foam formation (column 4, lines 1-15).

Because Frensch et al. teaches that foam formation is disturbing, it would have been obvious to one of ordinary skill in the art to have used the antifoaming agent of Frensch et al. in the coating dispersion of Jordan in order to obtain a capsule with no foam formation.

Response to Arguments

13. Applicant's arguments with respect to claims 1-56 have been considered but are moot in view of the cancellation of said claims, and the new ground(s) of rejection for the new claims.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SHF

Sow-Fun Hon
02/14/03

/Harold Pyon/
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1772
2/24/03